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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,988	03/16/2001	Gerhard Scheuch	RVOS-E1341US	7304

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EXAMINER	
DAWSON, GLENN K	

ART UNIT	PAPER NUMBER
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/810,988	SCHEUCH ET AL.	
	Examiner	Art Unit	
	Glenn K. Dawson	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-25,28-30 and 35-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-25,28-30 and 35-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 March 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-25,28-30 and 35-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The original specification does not provide support for the limitation of "controlling an air flow through the inhalation device using the inhalation device during the controlled inhalation".

The original specification does not provide support for the limitation of controlling the air flow velocity, or the use of a regulator to control air flow, or two conduits and regulator being in a housing, Or a venturi in the primary conduit.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the two

conduits and regulator being in a housing, Or a venturi in the primary conduit must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 24,25,28,38-40 and 42-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Brooker-6269810.

Brooker discloses a method for administering a controlled inhalation of an aerosol for a patient during breathing maneuvers including inputting into an inhalation device a plurality of parameters which include both aerosol and patient specific parameters, individually adjusting the inhalation device to the patient by adapting a dosage of an aerosol on the basis for the previous parameters by evaluating the parameters and adjusting a flow or tidal volume of the device based on the aerosol parameters such that an optimal dose of the aerosol is delivered to a specific location in the lungs during controlled inhalation and controlling the air flow through the device using the device

during controlled inhalation. See col. 6 lines 12-51; col. 7 lines 19-48, col. 12 lines 24-42 and col. 13 line 40-col. 14 line 20. The tidal volume and capacity are previously determined by pulmonary tests. The data used to program the device includes aerosol parameters, device parameters and patient specific parameters-col. 7 lines 32-48.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brooker-‘810 in view of Servidio, et a.-5598838.

Brooker discloses the invention as claimed with the exception of the modem. Servidio discloses that it was known to upload or download data to a respiratory device via a modem. It would have been obvious to have provided the system of Brooker with a modem in order to be able to provide the device with data remotely.

Claims 22,29,30,35,36,37 and 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brooker-‘810 in view of Willemot-5560353.

Brooker discloses the method as claimed with the exception of the use of a smart card or memory card to program the inhalation device. Willemot discloses that it was known to use such memory cards as input devices for inhalation devices. It would have been obvious to have had a physician program patient and drug data, for example, onto a memory card for placement into a reading device connected to the control means of the inhalation device, as this allows for safe transmission and a proper treatment regimen for each specific patient. Providing the device the capability to read and alter the controls of the inhalation device using the data from the card would have increased the effectiveness and adaptability of the device to facilitate the device in its use by different patients. One of skill in the art would have had every reason to expect success in achieving the predictable result of making the system more user friendly and more adaptable to different patients and drug treatment regimens.

Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brooker-‘810 as applied to claim 25 (and Brooker in view of Willemot as applied to claim 45) above in view of Howe, et al.-6070573.

Brooker or Brooker in view of Willemot discloses or make obvious the invention as claimed with the exception of the venturi. Howe teaches that it

was known to employ a venturi in a similar device. It would have been obvious to have used a venturi in Brooker's (or Brooker in view of Willemot) 's device, in order to eliminate the possibility of the patient increasing or decreasing the flow thus eliminating the possibility of over or under dosage.

Claims 24,25,28,38-40 and 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brand-6606989 (via WO98/52633) in view of Brooker-'810.

Brand discloses a method for administering a controlled inhalation of an aerosol for a patient during breathing maneuvers; however, the controlling of the air flow through the device during the controlled inhalation is not disclosed. The hardware of the system seems to be similar to that of the applicant with the exception of the modifications involving the controlling and adjustability with respect to the individual patient. However, Brooker discloses inputting into an inhalation device a plurality of parameters which include both aerosol and patient specific parameters, individually adjusting the inhalation device to the patient by adapting a dosage of an aerosol on the basis for the previous parameters by evaluating the parameters and adjusting a flow or tidal volume of the device based on the aerosol parameters such that an optimal dose of

the aerosol is delivered to a specific location in the lungs during controlled inhalation and controlling the air flow through the device using the device during controlled inhalation.

It would have been obvious to have modified the method taught by Brand to include the hardware and software changes taught by Brooker which are necessary to allow for the inputting of aerosol and patient specific parameters into the inhalation device to cause it to alter the air flow through the device depending on the patients requirements, as this would allow for specific tailoring of the accurate delivery of the aerosol medication to the particular patient's needs. This would greatly increase the accuracy of the correct dosing to any particular patient.

Claims 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brand-6606989 (via WO98/52633) in view of Brooker-'810, and further in view of Servidio, et al.-'838.

Brand as modified by Brooker makes obvious the invention as claimed with the exception of the modem. Servidio discloses that it was known to upload or download data to a respiratory device via a modem. It would have been obvious to have provided the system of Brand and Brooker with a modem in order to be able to provide the device with data remotely.

Claims 22,29,30,35,36,37 and 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brand-'989 in view of Brooker-'810, and further in view of Willemot-5560353.

Brand as modified by Brooker makes obvious the method as claimed with the exception of the use of a smart card or memory card to program the inhalation device. Willemot discloses that it was known to use such memory cards as input devices for inhalation devices. It would have been obvious to have had a physician program patient and drug data, for example, onto a memory card for placement into a reading device connected to the control means of the inhalation device, as this allows for safe transmission and a proper treatment regimen for each specific patient. Providing the device the capability to read and alter the controls of the inhalation device using the data from the card would have increased the effectiveness and adaptability of the device to facilitate the device in its use by different patients. One of skill in the art would have had every reason to expect success in achieving the predictable result of making the system more user friendly and more adaptable to different patients and drug treatment regimens.

Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brand-'989 in view of Brooker-'810, and further in view of as applied to claims 25 and 45 above, and further in view of Howe, et al.-6070573.

Brand as modified by Brooker make obvious the invention as claimed with the exception of the venturi. Howe teaches that it was known to employ a venturi in a similar device. It would have been obvious to have used a venturi in Brand/Brooker's device in order to eliminate the possibility of the patient increasing or decreasing the flow thus eliminating the possibility of over or under dosage.

Response to Arguments

Applicant's arguments with respect to all of the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply

is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K. Dawson whose telephone number is 571-272-4694. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd E. Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Glenn K Dawson
Primary Examiner
Art Unit 3731

Gkd
12 February 2008

/Glenn K Dawson/
Primary Examiner, Art Unit 3731